

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION**

ROY WILMOTH, JR.

PLAINTIFF

v.

CIVIL ACTION NO. 3:20-CV-120-NBB-RP

**ALEX M. AZAR, II, in his official
capacity as Secretary of the U.S.
Department of Health and Human Services**

DEFENDANT

REPLY IN FURTHER SUPPORT OF MOTION TO DISMISS

In his Complaint, Roy Wilmoth, Jr. – a Medicare beneficiary and the only plaintiff in this case – challenges a decision of the Medicare Appeals Council that denied his claim for the rental of a medical device known as the Optune System, manufactured by Novocure, Inc., for the period of April 19, 2018 through June 19, 2018. While the Council denied the claim, it ordered Novocure responsible for the charges. Mr. Wilmoth has no legal liability for the charges. Nevertheless, Mr. Wilmoth seeks an order for the Court directing the Secretary of the Department of Health and Human Services to cover the claim. He also seeks an order requiring the Secretary to find the Optune System is a covered benefit in the future.

The Secretary moved to dismiss the Complaint under Federal Rules of Civil Procedure 12(b)(1) and (6) on grounds that Mr. Wilmoth lacks standing because he has not suffered an actual injury and his Complaint fails to allege facts that state a cognizable claim. Docket 42. In opposition, Mr. Wilmoth does not overcome the grounds for dismissal. Docket 44.

First, Mr. Wilmoth's argument that the denial of his statutory right to Medicare benefits is sufficient to confer standing is inconsistent with Supreme Court precedent. In *Spokeo, Inc. v. Robbins*, 136 S.Ct. 1540, 1549 (2016), and more recently in *Thole v. U.S.*

Bank N.A., 140 S.Ct. 1615, 1619 (2020), the Supreme Court emphasized that an alleged violation of a statutory right alone – in the absence of any actual or imminent injury – does not satisfy Article III’s standing requirement.

Second, Mr. Wilmoth’s argument that he has suffered an injury because, if the denial of the subject claim is not reversed, he could be made liable for future claims, have treatment conditioned on his personal liability, and/or be charged with present knowledge of the denial, thereby precluding recovery on future claims, is likewise without merit. Wilmoth does not know if his future claims will be denied; and in fact, he alleges his subsequent claims have been paid. Docket 33, p. 6-8. Further, the Local Coverage Determination¹ for the Optune System was revised in September 2019 to provide coverage. AR-052-73. Equating speculative future harm with concrete injury is also inconsistent with Article III standing.

Third, Wilmoth fails to state a claim based on a denial of future benefits, as such an order would bypass the exhaustion requirements in 42 U.S.C. § 405(g). Advisory opinions on future coverage are not permitted. *Heckler v. Ringer*, 466 U.S. 602, 621-622 (1984). Mr. Wilmoth’s Complaint should be dismissed.

1. Wilmoth Lacks Standing Because the Statutory Right to Medicare Benefits – in the Absence of Actual or Imminent Harm – is Insufficient to Satisfy Article III’s Standing Requirements

The Secretary moved to dismiss the Complaint on grounds that the Court lacks standing because Wilmoth has no financial responsibility for the medical charges at issue,

¹ LCDs are decisions made a Medicare Administrative Contractor (MAC) on whether to cover a particular item or service in a MAC’s jurisdiction in accordance with § 1862(a)(1)(A) of the Social Security Act. See <https://www.medicare.gov/claims-appeals/local-coverage-determinations-lcd-challenge#:~:text=What's%20a%20%22Local%20Coverage%20Determination,of%20the%20Social%20Security%20Act.>

and any relationship between the subject claim denial and Wilmoth's financial liability for any future medical charges is speculative.

The United States Constitution limits federal court jurisdiction to actual cases or controversies. *Raines v. Byrd*, 521 U.S. 811, 818 (1997); Art. III, § 1. Standing to sue is a doctrine derived from this limitation on judicial power. *Spokeo, Inc. v. Robins*, 136 S.Ct. 1540, 1547 (2016). The "irreducible constitutional minimum" of standing consists of three elements: the plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Id.*, citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). The plaintiff bears the burden of establishing these elements. *Id.*

Wilmoth is unable to satisfy the "irreducible constitutional minimum" of standing by alleging only the violation of his statutory right to Medicare coverage. In his opposition, Wilmoth says that, due to the denial of his "Congressionally created entitlement to Medicare coverage, he has suffered an injury [that] can be addressed by a decision ordering coverage." Docket 44, p. 2. Wilmoth's contention is inconsistent with the cases he cites, and is inconsistent with Supreme Court precedent. *See Spokeo, supra*.

A. The Cases Relied On by Wilmoth Do Not Stand For the Proposition That Standing Can Be Conferred by Congress in the Absence of Actual or Imminent Harm

In opposition, Wilmoth asserts that "Congress may create a statutory right or entitled the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially cognizable injury in the absence of a statute." Docket 44, p. 2. He then cites three Supreme Court cases in support of his contention: *Warth v. Seldin*, 422 U.S. 490 (1975); *Linda R.S. v. Richard D.*, 410 U.S. 614, 617, n.3 (1973); and *Heckler v. Ringer*, 466 U.S. 602, 620 (1984). Docket 44, p. 2.

In *Warth v. Seldrin*, plaintiffs (taxpayers, low-income residents and various organizations of Rochester, New York) alleged that an adjacent town's zoning ordinances violated the Constitution and civil rights laws because they effectively excluded low and moderate-income persons from living in the town. *Id.* at 493-495. In affirming the district court's dismissal based on a lack of standing, the Supreme Court reasoned: "Congress may grant an express right of action to persons who otherwise would be barred by prudential standing rules. Of course, Article III's requirement remains: *the plaintiff still must allege a distinct and palpable injury to himself . . .*" *Id.* at 501 (emphasis added). *Warth* does not, as Wilmoth says, stand for the proposition that Congress can vitiate Article III's injury-in-fact standing requirement.

Wilmoth also relies on a footnote in *Linda R.S. v. Richard D.* in support of his contention that a statutory violation, by itself, is sufficient to satisfy Article III's standing requirements. *Linda R.S.* involved a constitutional challenge to a state criminal statute by a woman who alleged that, if the statute were declared unconstitutional, she could obtain child support for her illegitimate child. *Linda R.S. v. Richard D.*, 410 U.S. at 615. The district court dismissed the case based on a lack of standing. The footnote cited by Wilmoth is in the middle of a paragraph that notes the confusing state of the law on standing. The paragraph ends by acknowledging the importance of the actual or imminent injury requirement for Article III standing: "Although the law of standing has been greatly changed in the last 10 years, we have steadfastly adhered to the requirement that, at least in the absence of a statute expressly conferring standing, federal plaintiffs must allege some threatened or actual injury resulting from the putatively illegal action before a federal court may assume jurisdiction." *Id.* at 617. In the footnote cited by Wilmoth, the Court noted that "Congress may enact statutes creating legal rights, the invasion of which creates

standing, even though no injury would exist without the statute.” The Court did not give examples. Wilmoth emphasizes only a portion of the footnote and takes it out of context. It cannot be inferred from this single quote that Congress can do away with the requirements for Article III standing.

The third Supreme Court case Wilmoth relies on for the proposition that “Medicare benefits are an entitlement created by Congress, the denial of which confers standing” is *Heckler v. Ringer*, 466 U.S. 602 (1984). Docket 44, p. 2. In *Heckler*, the plaintiffs were Medicare claimants who were challenging the Secretary’s ruling that the type of surgery they had undergone was not reasonable and necessary. One of the plaintiffs wanted to have the surgery but alleged the Secretary’s decision precluded him from doing so and he therefore sought an injunction requiring the Secretary to declare the surgery was reasonable and necessary. *Id.* at 620. The Court interpreted the plaintiff’s claim as essentially one requesting the payment of future benefits. *Id.* at 620-621. The Court then held that Congress clearly foreclosed the possibility of declaratory judgment actions in this context because they would bypass the exhaustion requirements under the Medicare Act, which provided that a claim could be filed only *after* a medical service was provided. *Id.* at 621. The Court refused to sanction a bypass of the statutory scheme via a judicial advisory opinion. *Id.* at 621-622. The Court held that because the plaintiff had not satisfied the non-waivable exhaustion requirements in § 405(g), the federal courts lacked jurisdiction over the claim. *Id.* at 626-627. *Heckler v. Ringer* does not support Wilmoth’s argument that the Medicare Act’s authorization for a dissatisfied beneficiary to sue in federal court, in the absence of actual injury, is sufficient to confer standing.

B. In Cases After Those Cited by Wilmoth, the Supreme Court Has Clarified That a Statutory Violation, On Its Own, Is *Insufficient* to Satisfy Article III's Standing Requirements

In 2009, the Supreme Court held that the “deprivation of a procedural right without some concrete interest that is affected by the deprivation ... is insufficient to create Article III standing.” *Summers v. Earth Island Institute*, 555 U.S. 488, 498 (2009). The Court further noted that “Congress’ role in identifying and elevating intangible harms does not mean that a plaintiff automatically satisfies the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right. Article III standing requires a concrete injury even in the context of a statutory violation.” *Id.*

In 2016, the Supreme Court made clear that Article III standing is a constitutional minimum that “requires a concrete injury even in the context of a statutory violation.” *Spokeo, Inc. v. Robbins*, 136 S.Ct. 1540, 1549 (2016). In *Spokeo*, the plaintiff alleged that the operator of a website known as a “people search engine” violated the Fair Credit Reporting Act because search results reported inaccurate information about him. *Id.* at 1546. The district court dismissed the complaint because plaintiff had not alleged an injury-in-fact. *Id.* The Ninth Circuit reversed, finding that Spokeo had violated plaintiff’s statutory rights and that plaintiff had a personalized interest in the handling of his credit information. *Id.* at 1545-1546. The Supreme Court held that the Ninth Circuit’s analysis was incomplete because it focused on particularity and overlooked concreteness. *Id.* While noting that it is possible for an intangible injury to satisfy the injury-in-fact requirement for standing, the Court made clear that Congress cannot abrogate the injury-in-fact component of standing: “Congress cannot erase Article III’s standing requirements by statutorily granting the right to sue to a plaintiff who would otherwise not have standing.” *Id.* at 1548.

More recently, in *Thole v. U.S. Bank N.A.*, 140 S.Ct. 1615, 1619 (2020), the Supreme Court reiterated that a statutory violation, in the absence of an actual or imminent injury, cannot satisfy Article III standing requirements. The plaintiffs in *Thole* were participants in a defined benefit retirement plan who alleged the defendants mismanaged the plan and who sought an order requiring them to reimburse the plan for its losses caused by their malfeasance. The Court noted plaintiffs had received all the retirement benefits they were entitled to so far, and because they were legally and contractually entitled to receive their benefits for the rest of their lives regardless of the value of the plan or the good or bad investment decision of the plan's fiduciaries, they were not likely to suffer a reduction of their benefits in the future. *Id.* at 1618. Plaintiffs argued that they had standing because ERISA gives participants (and others) a cause of action to sue for restoration of plan losses and other equitable relief. *Id.* at 1620. But the Court found this was insufficient to confer standing because plaintiffs had not suffered a concrete injury. *Id.* at 1619-1620, citing *Spokeo, supra*, 136 S. Ct. at 1549, and *Raines, supra*, 521 U.S. at 820, n.3. The Court further held that an interest in attorney fees does not create Article III standing where none exists on the underlying merits. *Id.*

C. The District Court Cases Cited By Wilmoth Should Not Be Followed Because They Were Issued Before, and Are Contrary To, Controlling Supreme Court Precedent

In his opposition, Wilmoth says that “[m]ultiple courts have rejected the notion that economic injury is a requirement for standing in Medicare claim denial cases,” citing cases from Vermont, New Hampshire, and New Mexico issued between 1986 and 2015. Docket 44, p. 2. These cases are either distinguishable or are no longer good law in light of *Spokeo* and *Thole*.

The most recent district court case cited by Wilmoth is *Ryan v. Burwell*, 2015 WL 4545806 (D. Vt. July 27, 2015). In this case, the plaintiffs were dual eligible for Medicare and Medicaid, and Medicaid paid the claims after Medicare denied them. *Id.* at 6. Plaintiffs filed suit for an order requiring the Secretary to cover the claims. The Secretary moved to dismiss, asserting plaintiffs' lack of standing based on their lack of injury in light of Medicaid's payment of the claims. *Id.* at 4. The court found that, while Medicaid paid the claims, under Medicaid's rules, the plaintiffs were still at risk of co-payments and recoupment of costs under Medicaid-specific rules for which there was no Medicare counterpart. *Id.* at 2. As a result, the court found that plaintiffs had standing because they faced a risk of economic liability even though Medicaid had paid the claims. *Id.* The court also noted that plaintiffs were seeking to protect a right to coverage that is theirs by statute. *Id.* at 5. The other district court cases cited by plaintiff employed similar facts and/or reasoning.

Ryan is distinguishable because payment of the plaintiffs' claims did not absolve their legal liability for the medical costs. In contrast, in the present case, Wilmoth has not articulated any actual or imminent harm resulting from the Council's order requiring Novocure to assume the costs. Novocure has no recoupment rights against Wilmoth for the subject claim. To the extent *Ryan* is interpreted as standing for the proposition that the Medicare Act authorizes suit in the absence of actual or imminent injury, it is contrary to the Supreme Court's holdings in *Spokeo* and *Thole*.

The district court cases cited by Wilmoth are also factually distinguishable as none of them involved the unique combination of circumstances present in this case, *i.e.*, none of these four cases involved the combination of (1) a beneficiary who was relieved of financial responsibility for the denied claims on appeal because the supplier had not issued an

advance beneficiary notice (ABN)²; (2) where the non-coverage LCD then applicable to the denied claims on appeal was later amended; (3) there were no claim denials after the claim at issue; and (4) where the supplier bore sole financial responsibility for the denied claims on appeal. *Id.*

Moreover, other district courts have held that a plaintiff whose treatment costs were paid by a third party has not established standing. *Pehoviack v. Azar*, 20-cv-661 (C.D. Cal., Docket 22); *Hull v. Burwell*, 66 F.Supp.3d 278, 282 (D. Conn. 2014) (no injury-in-fact arising from Medicaid paying benefits rather than Medicare); and *Estate of Lake v. Secretary of HHS*, 1989 WL 200974 (D.N.H. Oct. 27, 1989) (because health care supplier was liable for costs, plaintiff lacked standing to sue for Medicare reimbursements).

D. Wilmoth Has Not Alleged an Actual Injury

Wilmoth has not alleged that he suffered actual harm, nor can he because the final decision of the Medicare Appeals Council ordered Novocure, Inc. – not Wilmoth – to pay the costs of the subject claim. Docket 41-1, p. 8. Win or lose this case, Wilmoth will not bear any liability for the subject medical treatment he received in 2018. Wilmoth does not dispute this in his opposition.

Further, Wilmoth has not alleged that he has had any claims denied since the claim at issue in this case. In fact, Wilmoth alleges that his subsequent claims have been granted. Docket 33, pp. 6-8. Thus, Wilmoth has not alleged an actual injury.

E. Wilmoth Has Not Alleged a Non-Speculative, Imminent Injury

In addition to failing to allege injury, Wilmoth does not allege any imminent harm sufficient to satisfy Article III standing requirements. Plaintiff asserts that if his claim

² See Docket 44, p. 5: “An ABN is a document putting the beneficiary on notice that the claim may not be paid (or paid in full) by Medicare and that, if so, that the beneficiary is personally liable for any amount not paid.”

denial is not reversed, he might be held personally liable for future claims under either 42 U.S.C. § 1395pp or an ABN issued by Novocure. Docket 44, p. 4-5.

Equating speculative future harm with concrete injury is inconsistent with Article III standing. The alleged “injury must be certainly impending to constitute injury in fact ... allegations of possible future injury are not sufficient.” *Clapper v. Amnest Intern. USA*, 568 U.S. 398, 409 (2013), citing *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990), see also *Texas v. United States*, 787 F.3d 733 (5th Cir. 2015).

Wilmoth does not know if his claims will be denied in the future, if a future ALJ will choose to ignore the revised LCD, or if Novocure will give him an advance beneficiary notice that would shift payment obligations for future treatments for him. *See Hull, supra*, 66 F.Supp.3d at 283. In fact, Wilmoth alleges injuries that are contingent on the actions of third parties. Docket 44, p 3-5. Because Wilmoth’s liability is dependent on not one, but a chain of decisions made by different actors, his alleged future harms are an “exercise in the conceivable,” but do not show a “factual showing of perceptible harm” sufficient for Article III standing. *Lujan, supra*, 504 U.S. at 566. The recent change in the LCD even further attenuates the potential for Wilmoth’s future liability for TTFT. The LCD was revised in September 2019 to include coverage for TTFT. AR-052-73. The Council’s decision makes clear that ALJs should give deference to the LCD. AR-004.

Even assuming that a claim denial were impending, which it is not, section 1395pp does not afford Plaintiff standing. Section 1395pp(b) states that “in the case of *comparable situations* arising thereafter with respect to such individual, [she] shall, by reason of such notice . . . be deemed to have knowledge that payment cannot be made for such items or services.” (emphasis added). There is no dispute that there was a significant change between the 2014 LCD, which categorically denied coverage for TTFT, and the 2019 LCD, which provides coverage for TTFT when certain criteria are satisfied. AR-004-005, 052-73.

It is highly unlikely that an ALJ would deem Plaintiff to have knowledge that his TTFT claim would be denied under the 2019 LCD, given a denial in different circumstances under the 2014 LCD.³ And, even in the unlikely event that Plaintiff were held personally liable, he could still appeal to federal court. Standing cannot be based upon the hypothetical, and distinctly unlikely, possibility that the instant claim denial could influence the decision of a judge to find Plaintiff personally liable at some unknown point in the future. *See, e.g., Hull*, 66 F. Supp. 3d at 282-83 (finding that plaintiff's potential liability under section 1395pp(b) was "wholly contingent upon the future acts or omissions of third parties" and failed to establish an impending injury).

Wilmoth also relies on the possibility that Novocure may try to use the denied claim for the April 19, 2018 through June 19, 2018 dates of service as an excuse to send him an ABN that will shift the risk of a future claim denial to him. Docket 44, p.3-5. While it is true that Medicare claim processing rules provide that a supplier can shift the financial risk of non-coverage to a beneficiary by issuing an ABN which gives advance written notice of the specific reason why an item probably will not be covered, 42 C.F.R. § 411.404(b), speculation about whether Novocure will do so, particularly in light of the alleged subsequent claim payments and the revised LCD, is insufficient to satisfy Article III standing requirements for Wilmoth's current case. *Whitmore*, 495 U.S. at 155.

In *California Clinical Laboratory Ass'n v. Secretary of HHS*, 104 F.Supp.3d 66 (D.D.C. May 20, 2015), a case involving a challenge under the Medicare Act to a LCD filed by a provider and beneficiary, the Secretary moved to dismiss based on a lack of standing. The court held that a statutorily-conferred right to file suit does not satisfy the injury-in-

³ Plaintiff's "Exhibit A" should be stricken or disregarded, because it is outside the administrative record and the Amended Complaint. *See* 42 U.S.C. § 405(g) (requiring review "upon the pleadings and transcript of the record"). In addition, an ALJ decision regarding another beneficiary and TTFT claims prior to the revised LCD is irrelevant.

fact requirement for constitutional standing purposes unless it confers a substantive right or entitlement. *Id.* at 76-78. The court gave FOIA as an example of a statute conferring such a right, reasoning that anyone whose request for information is denied has been injured-in-fact for standing purposes. *Id.* at 76. The court contrasted the right to file a challenge to a LCD, which it deemed a procedural right. *Id.* Reasoning that because the beneficiary plaintiffs had not been charged for any of the subject testing expenses, and because they did not allege their physician would imminently order further clinical testing (but, even if they had, they had not alleged there was a substantial probability that Medicare would once again deny coverage), and because the plaintiffs did not allege that they would receive a notice from the provider shifting the cost of future testing to them, plaintiffs failed to allege they had suffered an injury-in-fact sufficient for satisfying Article III standing requirements. *Id.* at 79-80.

Similarly, Wilmoth has not alleged that he has ever actually been deprived of or charged for TTFT treatment. He cannot establish that there is a substantial probability that Medicare will deny any of his future TTFT claims because the revised LCD favors coverage, and he has not alleged a claim denial since the subject claim. He does not allege that he has received an ABN, so there is no viable basis for asserting future injury as a result of the Secretary's actions. As already stated, the speculative chain of possibilities about the potential for future claim denials and possible ABNs is so tenuous that it cannot satisfy Article III injury-in-fact standing requirements.

II. Wilmoth Has Failed to State a Claim for Relief

Wilmoth fails to state a claim for a violation of the Medicare Act because he has alleged no injury. The subject claim was ordered to be paid by Novocure and Wilmoth has no legal liability for the subject claim. Wilmoth has failed to state a claim based on a denial of future benefits, as such an order would bypass the exhaustion requirements in 42 U.S.C.

§ 405(g). Advisory opinions regarding future coverage are not permitted. *Heckler v. Ringer*, 466 U.S. 602, 621-622 (1984); *Porzecanski v. Azar*, 943 F.3d 472 (D.D.C. 2019) (denying beneficiary's claim for declaratory and injunctive relief regarding future Medicare claims on the grounds the Medicare Act requires all claims to be channeled through the Medicare claims process). Further, any order providing that an ALJ or the Secretary is collaterally estopped by an earlier decision of the Secretary is nothing more than an impermissible end-run around the exhaustion requirements in § 405(g) and the prohibition against advisory opinions.

III. Conclusion

For these reasons, Wilmoth lacks standing to assert his claims and the allegations in the Complaint fail to state a cognizable claim. These deficiencies cannot be cured. The Complaint should be dismissed with prejudice.

William C. Lamar
United States Attorney

By: Stuart S. Davis (MSB #103224)
Assistant United States Attorney
Northern District of Mississippi
900 Jefferson Avenue
Oxford, Mississippi 38655
t: 662.234.3351
f: 662.234.3381
e: stuart.davis@usdoj.gov